PUBLIC NOTICE

Federal Communications Commission
445 12th St., S.W.
Washington, D.C. 20554

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Federal Communications Commission (FCC) and Food and Drug Administration (FDA) to Hold Public Meeting on Regulatory Issues Arising from Health Care Devices that Incorporate Radio Technology Wireless Communications Networks; Comments Sought

FCC Docket No. ET 10-120
FDA Docket No. FDA-2010-N-0291

Comment Date: June 25, 2010

The Federal Communications Commission (FCC) and Food and Drug Administration (FDA) are seeking comment on converged communications and health care devices impact on regulation. A public meeting to discuss topics related to this issue is scheduled for July 26 and 27, 2010.

The Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) are jointly sponsoring a public meeting entitled: "Enabling the Convergence of Communications and Medical Systems: Ways to Update Regulatory and Information Processes." The purpose of this meeting is to gather input from the medical, telecommunications, and device manufacturing industries; practitioners, patients, and other users; and other relevant stakeholders to identify the challenges and risks posed by the proliferation of new sophisticated medical implants and other devices that utilize radio communications to effectuate their function, as well as challenges and risks posed by the development and integration of broadband communications technology with health care devices and applications. The information gathered will be used to enhance the coordination between FDA and FCC for such devices and applications, and clarify and delineate the respective areas of expertise and jurisdiction between the agencies. This information will simplify and expedite the introduction of new and important medical technologies and techniques while maintaining safety and efficacy levels appropriate to the various technologies and devices. FDA and FCC are seeking input on these topics and request information and comments responsive to a number of specific questions related below. Additional information and comments deemed pertinent to this general area of inquiry by any commenter but not specifically addressed in our listed questions may also be submitted. While the general format for this meeting is outlined in this document, the details will be further informed by the comments received, and a final agenda will be published on the Internet in the future.

Date and Time: The public meeting is scheduled for July 26 and 27, 2010, from 8:00 a.m. to 5:30 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on July 19, 2010. Submit written or electronic comments by June 25, 2010, 5:00 p.m. EDT.

Location: The public meeting will be held at the FCC Commission Meeting Room, 445 12th St., SW, Washington, DC

Contact Persons:

FDA: Bakul Patel, bakul.patel@fda.hhs.gov, 301-796-5528
Food and Drug Administration, Center for Devices and Radiological Health
10903 New Hampshire Avenue, Bldg. 66, rm. 3543, Silver Spring, MD 20993

FCC: Bruce Romano, bruce.romano@fcc.gov, 202-418-2470
Federal Communications Commmission, room 7-C140
445 12th St., SW, Washington, DC 20554

Registration and Requests for Oral Presentations: **The meeting is open to the public.** Registration requests must be received by 5 p.m. on July 19, 2010. Interested persons may register by e-mailing fcc-fdameeting@fcc.gov. Registrants must provide the following information: (1) name, (2) title, (3) company or organization, (4) mailing address, (5) telephone number, and (6) e-mail address. Registrants will receive confirmation once they have been accepted. Persons interested in attending the meeting are encouraged to register as registrants will have seating priority in order of registration and can be best assured of receiving information by e-mail regarding any changes that may occur in meeting particulars. Also, registration will be required for all speakers. Overflow rooms with closed circuit video monitors will be provided as needed to accommodate the public. FDA and FCC may limit the number of registrants from each organization based on space limitations.

If you wish to make an oral presentation during any of the open comment sessions at the meeting, you must indicate this at the time of registration. FDA and FCC have included specific questions for comment in section III of this document, Questions for Comment. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open comment session focused on the topic at hand, each oral presentation should address only the topic specified for that session. FDA and FCC will do their best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA and FCC will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Reasonable accommodations for people with disabilities are available upon request. The request should include a detailed description of the accommodation needed and contact information. Please provide as much advance notice as possible; last minute requests will be accepted, but may not be possible to fulfill. Send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY).

Comments: FDA and FCC are holding this public meeting to gather information on a number of questions regarding regulatory challenges and safety for patients and other users of medical devices that include radio elements and of systems that can be tied into broadband communication networks. The deadline for submitting comments related to this public meeting is June 25, 2010, 5:00 p.m. EDT.

Any interested persons may submit electronic comments to http://www.regulations.gov, or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and to the Federal Communications Commission, Office of the Secretary, 445 12th Street, SW, Room TW-A235, Washington, DC 20554 . Submit one paper copy of mailed comments if you are submitting to FDA and two paper copies of mailed comments if you are submitting to FCC, except that individuals may submit one paper copy to each address. Identify comments with the docket numbers found in

the heading of this document. In addition, when responding to specific questions as outlined in this document, please identify the question you are addressing. Received comments are available at all times via the Federal eRulemaking Portal: http://www.regulations.gov. They also may be seen in FDA's Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday or at the Federal Communications Commission, Reference Information Center, CY-A257, Monday through Thursday between the hours of 8 a.m. and 4:30 p.m. and on Fridays between the hours of 8 a.m. and 12:00 Noon.

SUPPLEMENTARY INFORMATION:

I. Background

There have been significant developments in recent years in medical and health care devices using radio technology to monitor various body functions and conditions, including critical elements, and to deliver treatment and therapy. There has also been an increasing proliferation of devices using established commercial communications networks, including those providing Internet connectivity, to communicate with care providers. Mobile devices like smartphones and personal digital assistants (PDAs) are transforming the transmission of information used by physicians to help manage patient care, including communication networks to relay information for patient health monitoring and decision support.

Examples of the latest implant or body-worn monitoring, therapeutic, and treatment technologies include blood glucose monitors and automated insulin pumps, heart monitors, pacemakers, defibrillators, and neural pathway replacements that stimulate muscle movement.

Examples of devices and applications that use commercial communications networks and represent the convergence of communications and medicine include a smartphone application that displays real-time fetal heartbeat and maternal contraction data allowing obstetricians to track a mother's labor and wearable wireless patch-like sensors that transmit health data over commercial wireless networks to practitioners, caregivers and patients.

These and other products cover a broad range of health care solutions. At one end, general-purpose communications devices such as smartphones, wireless routers and certain video-conferencing equipment are regulated by FCC. At the other end, medical devices that critically monitor patient health or provide treatment or therapy are regulated by FDA. Devices that do provide critical care and also use communications, such as life-critical wireless devices like remotely controlled drug-release mechanisms, are regulated by both agencies. In addition, device applications that would not be governed by FCC but transmit over wireless networks might warrant FDA oversight, while FCC might have better capability to assess the reliability of their communications capability.

FCC and FDA recognize the need to work with all stakeholders to identify pathways and strive to improve processes that will help continue to spur innovation in these areas while maintaining safety and effectiveness and promoting public health.

II. Public Meeting

The objective of this meeting is to gather information and to better understand issues and perspectives from various stakeholders so the agencies can identify potential areas where each agency's jurisdiction can be identified and clarified for affected parties, collection and assessment of each agency's respectively appropriate information can be improved, expertise can be shared, and regulatory approval can be coordinated and simplified. These concerns relate both to devices

operating on designated frequencies and to convergent medical device and information technology, as described previously. This includes challenges faced by manufacturers and innovators in ensuring compliance with various regulatory requirements and risks associated with medical device systems using spectrum shared by other medical devices, using spectrum shared by other types of devices and services, and using broadband communication capabilities.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at http://www.regulations.gov and in the FCC and FDA public reference rooms listed previously. This information will also be available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (select the appropriate meeting from the list), and from http://www.fcc.gov/workshops (select the appropriate meeting from the list).

III. Questions for Comment

FDA and FCC are planning to focus the public meeting on the following topics:

A. Data integrity and reliability issues arising from the use of allocated spectrum, the use of unlicensed devices, and the use of commercial networks and applications, and needs, uses, and risks for 'medical-grade' wireless technology and communications.

B. Medical device and system security issues – inadvertent and intentional intrusion – nonfunction and malfunction.

C. Trends in medical devices using allocated spectrum and using unlicensed operation, and medical devices and applications using commercial networks. Consideration of various wireless networking scenarios and use cases.

D. Risks Management:
   a. The need to define levels of "criticality" of device function that can be used for determining reliability requirements.

   b. Environmental factors and delivery setting – hospitals, users, clinics, home, travel, *etc.*

E. Views on current FDA and FCC regulatory requirements:
   a. Relationship between FDA approval/clearance and FCC certification of applications, post market and compliance requirements.

Each of the previous topics will cover

1. Defining topics and scope;

2. Identifying the needs, goals and stakeholders; and

3. Recommendations.

FCC and FDA are seeking comments on the topics and soliciting suggestions on alternate or additional topics that commenters deem closely related. All comments and suggestions will be considered with the constraint of completing the workshop in no more than two days. To be considered, topics proposed must be relevant to the objective and intent of the workshop.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at the Federal eRulemaking Portal: http://www.regulations.gov. Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. Transcripts may also be viewed at the Federal Communications Commission, Reference Information Center, Monday through Thursday, between the hours of 8 a.m. and 4:30 p.m. and on Fridays between the hours of 8 a.m. and 12:00 Noon.